

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

UNOMEDICAL A/S,

Plaintiff,

vs.

SMITHS MEDICAL MD, INC.,

Defendant.

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CASE NO. 1:09-CV-04375

Judge John W. Darrah

Magistrate Judge Sidney I. Schenkier

**MEMORANDUM IN SUPPORT OF UNOMEDICAL’S MOTION TO STRIKE SMITHS’
FOURTH, SEVENTH AND NINTH AFFIRMATIVE DEFENSES AND TO DISMISS
SMITHS’ NON-PATENT COUNTERCLAIMS**

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I. INTRODUCTION

Smiths' 152-paragraph Answer, Amended Defenses, and Amended Counterclaims parades a host of allegations of bad faith and deceptive intent by Unomedical, yet does not support them with anything close to the pleading with particularity standard required for such serious allegations. For these and other pleading deficiencies, the Court should strike or dismiss multiple affirmative defenses and counterclaims brought by Smiths.

Specifically, Smiths' Fourth, Seventh, and Ninth affirmative defenses for unenforceability, bad faith litigation, and inequitable conduct, respectively, do not plead facts sufficient to support a reasonable inference of bad faith or deceptive intent. Indeed, these defenses are not supported by a pleading of *any* facts in this regard. Further, the requisite allegations of the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO" is nowhere to be found in Smiths' Answer. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

Smiths' antitrust counterclaims based on *Walker Process* and sham litigation allegations (Counterclaims VI-VIII) likewise are not pled with the requisite particularity. Instead, they are predicated on the same bare-boned allegations of Smiths' inequitable conduct pleadings. Moreover, Smiths has not pled any facts sufficient to show this case is objectively baseless as required to support a sham litigation claim. Smiths' invalidity allegations fall short as they rely on references that were considered by the Patent Office during the prosecution, while the infringement allegations consist of nothing more than mere garden-variety denials.

Smiths' false advertising counterclaims (Counterclaims IV-V) fail as well because there is no pleading of facts sufficient to show the identity of the person making the alleged misrepresentation, nor are facts pled sufficient to show the time, place, and content of the alleged misrepresentation, or the method by which the alleged misrepresentation was made.

Smiths' tortious interference claim (Counterclaim III) similarly is not supported by the facts required to show bad faith.

Smiths' pleading is legally insufficient requiring that the Court grant Unomedical's motion to dismiss and strike the defenses and counterclaims, as detailed below.

II. SMITHS' AFFIRMATIVE DEFENSES AND COUNTERCLAIMS AT ISSUE

Smiths' Fourth Affirmative Defense – Invalidity And/Or Unenforceability: Smiths' Fourth Affirmative Defense alleges only that “[e]very asserted claim of the ’493 patent is invalid and/or unenforceable for failure to comply with United States patent law, 35 U.S.C. § 1 *et seq.*” (Dkt. 19 ¶ 15).¹ No facts whatsoever are included to support this invalidity or unenforceability defense.

Smiths' Seventh Affirmative Defense – Bad faith Litigation: Smiths' Seventh Affirmative Defense asserts that Unomedical is engaging in “bad faith” litigation to enforce one or more patents it “knows” to be invalid and not infringed, but it does not set forth any facts about the alleged bad faith or the basis for Unomedical's alleged “knowledge.” (Dkt. 19 ¶ 18)

Smiths' Ninth Affirmative Defense – Inequitable Conduct And Fraud On The Patent Office: Smiths' Ninth Affirmative Defense asserts inequitable conduct alleging that Unomedical's attorney and unnamed others associated with the prosecution of U.S. Patent No. 7,407,493 (“’493 patent”) intentionally mislead the Patent Office by burying three references “within a large body of disclosed references and thereby hid it from the Patent Office with intent to deceive the Patent Office” (Dkt. 19 ¶ 22). Specifically, Smiths alleges that U.S. Patent Nos. 5,451,210 (“the ’210 patent”); 5,248,301 (“the ’301 patent”); and 6,613,064 (“the ’064 patent”) are material prior art; that Unomedical's attorney was “aware of [those patents] and

¹ “Dkt. 19” refers to Docket No. 19, which is Smiths Medical ASD, Inc.'s Answer to Unomedical A/S's Complaint, Amended Defenses, and Amended Counterclaims filed with this Court on August 24, 2009.

[their] materiality, because Doe disclosed [them to the PTO]” but they were “buried” among the 461 total prior art references. (Dkt. 19 ¶ 22).

Smiths’ Third Counterclaim – Tortious Interference With Prospective Economic Advantage: Smiths’ third counterclaim alleges that “[o]n information and belief,” Unomedical intentionally and wrongfully interfered with Smiths’ ability to enter into contract or business relations by: making false statements to third parties, amending pending patent claims to cover Smiths’ existing products, and trying to direct Smiths’ sale of certain products to or away from certain prospective purchasers. (Dkt. 19 ¶ 41). Smiths further alleges “[o]n information and belief” that the false statements were made in bad faith because Unomedical knew that its ’493 patent was invalid, unenforceable and/or not infringed. (Dkt. 19 ¶ 42). No facts supporting Smiths’ “information and belief” of bad faith are provided.

Smiths’ Fourth And Fifth Counterclaims – False Advertising: Smiths’ Fourth and Fifth Counterclaims allege that in bad faith, Unomedical “made false statements in advertising or promotion distributed in interstate commerce, to the effect that Smiths’ products infringe the ’493 patent,” in violation of the Lanham Act and the Minnesota Deceptive Trade Practices Act (“MDPTA”). (Dkt. 19 ¶¶ 47-59). Notably, Smiths does not identify these statements, who made them and to whom, when they were made, or in what advertisement they were made.

Smiths’ Sixth, Seventh And Eighth Counterclaims – Antitrust: Smiths’ monopolization and attempt to monopolize counterclaims are based on *Walker Process* and sham litigation allegations under § 2 of the Sherman Act and Minnesota antitrust law. The *Walker Process* fraud allegation is based on three inequitable conduct claims. The first is that Unomedical drafted claims that read on the accused CLEO[®] infusion set. (Dkt. 19 ¶¶ 68-70). Smiths alleges “[o]n information and belief” that Unomedical knew or knows now that the

claims allegedly do not comply with 35 U.S.C. § 112. (Dkt. 19 ¶¶ 69-70). No facts supporting Smiths’ “information and belief” are pled.

The second inequitable conduct assertion includes the same “burying” allegations made in Smiths’ Ninth Affirmative Defense discussed above. (Dkt. 19 ¶¶ 72-102).

The third inequitable conduct allegation is that Unomedical and those associated with the prosecution of the ’493 patent withheld certain references from the Patent Office during the prosecution of the ’493 patent. (Dkt. 19 ¶¶ 103-109). Smiths’ allegation does not identify who withheld the references or the basis for Smiths’ “information and belief” that they were “knowingly withheld . . . with an intent to deceive the Patent Office.” (Dkt. 19 ¶¶ 103-105). One of the references Unomedical is accused of withholding is U.S. Patent Application Publication No. 2001/0039387 (“the ’387 publication”), which is the published patent application that led to the ’064 patent. (Dkt. 19 ¶¶ 94-95). Even though the ’064 patent and the ’387 publication include the “same disclosure,” Smiths nonetheless accuses Unomedical of both “burying” that disclosure by submitting the ’064 patent in an IDS and at the same time also withholding that same disclosure by failing to submit the ’387 publication. (Dkt. 19, Compare ¶ 22.C with ¶¶ 104-105).

III. GOVERNING LEGAL PRINCIPLES

When evaluating a motion to dismiss, a court must determine whether the allegations plausibly suggest that the complainant has “a right to relief above the speculative level” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544-45, 555 (2007). “A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1940 (2009). That is, a claim requires sufficient facts to show more than “a sheer possibility that a defendant has acted unlawfully” *Id.* at 1949. A complaint with facts “merely consistent with a defendant’s

liability . . . stops short of the line between possibility and plausibility of entitlement to relief.”

Id.

While, a complaint pled under Rule 8(a) “does not need detailed factual allegations . . . a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitlement to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (citations omitted). Further, certain causes of action, including fraud, must be pled with particularity pursuant to Fed. R. Civ. P. 9(b). Such claims require pleading the “who, what, when, and where” of the cause of action. *See, e.g., MPC Containment Sys., Ltd., v. Moreland*, No. 05 C 6973, 2006 WL 2331148, at *2 (N.D. Ill. Aug. 10, 2006).

Motions to strike affirmative defenses are decided by a three-step analysis. *Bobbitt v. Victorian House, Inc.*, 532 F. Supp. 734, 737 (N.D. Ill. 1982). First, the Court should consider whether the matter is appropriately pled as an affirmative defense. *Id.* Second, if an appropriate affirmative defense, the Court should consider whether it was appropriately pled pursuant to Fed. R. Civ. P. 8(a) or 9(b). *Id.* Lastly, the Court should determine whether the affirmative defense withstands the Rule 12(b)(6) standard for dismissal. *Id.*

IV. ARGUMENT

A. Smiths’ Inequitable Conduct Defense And Counterclaims Should Be Dismissed For Failure To Meet The Pleading Standards Of *Exergen* (Fourth And Ninth Affirmative Defenses And Counterclaims VI-VIII)

1. Pleading Standards For Inequitable Conduct

To maintain inequitable conduct claims, Smiths must plead facts showing that (a) the applicant made a misrepresentation or omission of material information to the Patent Office with (b) the specific intent to deceive the examiner. *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

Smiths must plead inequitable conduct with particularity pursuant to Fed. R. Civ. P. 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009). To comply with Rule 9(b) pleading standard, Smiths must plead the “who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp.*, 575 F.3d at 1328. In *Exergen*, the Federal Circuit explained that:

a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) *knew* of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a *specific intent to deceive* the PTO.

Id. at 1328-29 (emphasis added.) Further, while knowledge and intent may be pled on “information and belief,” Smiths must set forth the specific facts providing the “information” or “belief.” *Id.* at 1330-1331. Thus, to meet the pleading standard for the knowledge component, Smiths must plead facts showing that a specific individual was aware of the specific portions of the allegedly misrepresented or withheld material reference. *Id.* Smiths must also plead facts showing or supporting a reasonable inference that this specific individual deliberately decided to withhold or misrepresent the allegedly material information to the examiner. *Id.*

Additionally, threshold levels of intent and materiality must both be pled. *Exergen Corp.*, 575 F.3d at 1330-31. The materiality of the allegedly withheld reference cannot lead to an inference of deceptive intent. *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1321 (Fed. Cir. 2010).

2. Smiths’ Burying Allegations Are Deficient

a. Smiths Failed To Plead That Unomedical Acted With An Intent To Deceive

Far from showing facts that support an intent to deceive the Patent Office examiner, Smiths’ allegations show that Unomedical sought to fulfill its duty of disclosure by submitting

the potentially material art of which it was aware. Smiths' attempts to conjure up a specific intent to deceive by pointing to the total number of submitted references, a request from the examiner to point out any references that the applicant "belie[ved] may be of particular relevance," and an errant inclusion of one irrelevant reference. (Dkt. 19 ¶¶ 100-103). These allegations fall short of a reasonable inference of deceptive intent.

Applicants are instructed by case law, as well as by the Patent Office, to err on the side of submitting references for review by the examiner. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995) ("Those who are not 'up front' with the PTO run the risk that years later, a fact-finder might conclude that they intended to deceive."); *see Manual of Patent Examining Procedure* § 2004 (8th ed. Rev. Jul. 2010) (hereinafter "MPEP") ("When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn't consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided."). "Close cases [of whether or not to submit a reference] should be resolved by disclosure, not unilaterally by the applicant." *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992). "Presumably, applicants will continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality." MPEP § 2001.04.

The obligation of disclosure is a continuing one; it exists throughout the prosecution of the application and extends to references found in other applications. MPEP §§ 2001, 2001.06(b). Therefore, the number of references submitted is not indicative of bad faith, but rather of an effort to comply with its ongoing duty to provide the art of which the applicant was aware and that may be relevant to examination.

In addition, where an examiner has initialed the Information Disclosure Statement (IDS) next to each of the references, the examiner is presumed to have reviewed and considered all of them. *See Molins*, 48 F.3d at 1177. In such circumstances, a claim of inequitable conduct based on burying is improper. *Prima Tek II, LLC v. Polypap S.A.R.L.*, 316 F. Supp. 2d 693, 710 (S.D. Ill. 2004), *rev'd on other grounds* 412 F.3d 1284 (holding there could be no burying because the examiner indicated that he considered all of the references submitted, thus there were no grounds to find inequitable conduct); *Haney v. Timesavers, Inc.*, 900 F. Supp. 1378, 1380-82 (D. Ore. 1995) (granting summary judgment of no inequitable conduct based on burying because “the court cannot infer an intent to deceive on the part of Haney from the manner in which the information was conveyed to the Patent Office when the information was, in fact, conveyed.”). Notably, Smiths has not pled that the Examiner did not consider the art cited by Unomedical. (Dkt. 19 ¶¶ 22, 72-103.) Nor could it do so because each of these references is identified on the face of the patent, which shows that the examiner *did* consider them. (*See* Dkt. 1, Ex. 1, '493 patent; MPEP §§ 609.05(b), 609.06.) As the Federal Circuit has made clear, “[a]n applicant can not be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner.” *Fiskars, Inc. v. Hunt Mfg., Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000); *Symbol Tech. v. Aruba Networks, Inc.*, 609 F. Supp.2d 353, 358-59 (D. Del. 2009) (holding that under Federal Circuit precedent, burying is an insufficient basis for alleging inequitable conduct as a matter of law).

Instead, Smiths suggests that Unomedical’s attorney breached her duty of candor by not responding to the examiner’s inquiry to “point out any particular references in the IDS which they belief (sic) may be of particular relevance to the instant claimed invention.” (Dkt 19 ¶ 22D). However, there is no authorization or obligation in the Manual of Patent Examining

Procedure or anywhere else that provides for such an inquiry or requires such a response.² The reason is clear: any statement about which art was more relevant would lead to an inequitable conduct claim by a defendant, such as Smiths.³ Indeed, an attorney may not wish to emphasize some references over others that the examiner or court may find more pertinent for fear of misleading an examiner. *See Litton Sys. v. Honeywell Inc.*, Nos. 90-93, 90-4823, 1995 WL 366468, at *37 (C.D. Cal. Jan. 6, 1995), *rev'd in part on other grounds*, 87 F.3d 1559 (Fed. Cir. 1996), *vacated and remanded*, 520 U.S. 111 (1997).

Lastly, Smiths alleges that the inclusion of the printed publication of the '493 patent application is evidence of an intent to deceive the PTO. (Dkt. 19 ¶ 103.) However, this is only one reference, and its inclusion is indicative of an error in the ministerial task of collecting the known references and filling out an IDS. At most, including the printed publication of the '493 patent amounts to a mistake, not evidence of intent to deceive. *See Kingsdown*, 863 F.2d at 875-76 (noting that ministerial tasks are more prone to errors due to inattention than to scienter).

b. Smiths Fails To Show That The Allegedly Buried References Are Not Cumulative

The Federal Circuit, in *Exergen*, also required parties pleading inequitable conduct to “identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record.” *Exergen*, 575 F.3d at 1329-30. As the Federal Circuit noted, “[s]uch allegations are necessary to explain both ‘why’ the withheld information is

² In 2000-01, the PTO eliminated the requirement of including a concise statement of the relevance of each prior art reference. *Symbol*, 609 F. Supp.2d at 358-59. While the PTO is authorized to request certain information pursuant to 37 C.F.R. § 1.105 it may not request an identification of prior art believed to be of particular relevance. As the MPEP explains, the request can only be directed to factual information and cannot seek opinions. MPEP § 704.11.

³ The reality of this statement is particularly appropriate in this case where one of Smiths' burying allegations is based on the '064 patent (Dkt. 19 ¶¶ 22, 91-99); but at the same time Smiths has also accused Unomedical of inequitable conduct based on knowingly withholding the *very same information* from the PTO based on not disclosing the '387 Publication (Dkt 19 ¶¶ 94-95, 104-108).

material and not cumulative, and ‘how’ an examiner would have used this information in assessing patentability.” *Id.* Smiths did not comply with this directive, and has not even pointed out which limitations were missing from the other prior art of record. Instead, Smiths merely pleads that each of the alleged buried references is “not cumulative to the prior art of record.” (Dkt. ¶¶ 22.A.iv, 22.B.iv, 22.C.v, 81, 89, 98).

c. Smiths Fails To Plead Facts Sufficient To Show That Unomedical Was Aware Of The Relevant Portions Of The Allegedly Buried References

Smiths never alleges that anyone associated with the prosecution of the ’493 patent was aware of the particular portions of the allegedly material references Smiths relies on. Instead, Smiths merely alleges that Doe was aware of each reference and its materiality because it was disclosed in the IDS. (Dkt. 19 ¶¶ 22.A.v., 22.B.v., 22.C.vi., 82, 90, 99.) However, under *Exergen*, mere awareness of the reference is insufficient to plead that Doe was aware of the alleged material portions of a reference. The Federal Circuit made clear that “one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material information contained in that reference.” *Exergen*, 575 F.3d at 1330.

Not surprisingly, in accordance with the Federal Circuit’s pronouncement in *Exergen*, the Patent Office’s Rules explain that a submission of a reference to the PTO is not an admission that the reference is, or is considered to be, material. 37 C.F.R. § 1.97(h). Smiths has not pled any facts to support a reasonable inference that Doe believed any particular reference was material, let alone any particular portions of the allegedly buried references were material.

3. Smiths’ Inequitable Conduct Theory Based On “Withholding” Prior Art And Written Description Fail To Meet The *Exergen* Pleading Standards

Smiths’ inequitable conduct pleading relating to the alleged withholding of prior art also fails to meet the “who, what, when, where, and how” requirements set forth in *Exergen*. (Dkt. 19

¶¶ 104-109). In *Exergen*, the Federal Circuit held that the “who” pleading requirement was not met by a general reference to “Exergen, its agents and/or attorneys.” *Exergen*, 575 F.3d at 1329. The same applies here where Smiths alleges that references were withheld by “Unomedical and/or those associated with the prosecution of the ’493 patent.” (Dkt. 19 ¶¶ 104-105). Further, merely pleading generally that the withheld references are “material” and “not cumulative to the information already of record” fails to meet the “how” pleading requirement. *Exergen*, 575 F.3d at 1329-30. Instead, the pleading should indicate “the particular claim limitations, or combination of limitations, that are supposedly absent from the information of record.” *Id.* Smiths’ mere pleading that the alleged withheld references are material and not cumulative does not meet the “how” requirement.⁴ (Dkt. 19 ¶¶ 106-109).

Smiths also fails to plead facts sufficient to support an inference of an intent to deceive. Instead, Smiths only pleads that “on information and belief,” Unomedical withheld the references “with an intent to deceive the Patent Office.” (Dkt. 19 ¶¶ 104-109). However, Smiths’ deceptive intent pleadings based on “information and belief” are inadequate because no specific facts upon which that belief is reasonably based are pled. *Exergen*, 575 F.3d at 1330-31 (deceptive intent not adequately pled where defendant’s “pleading provides neither the ‘information’ on which it relies nor any plausible reasons for its ‘belief.’”). In *Exergen*, the Federal Circuit found that a reasonable inference of deceptive intent was not supported by pleading facts that an applicant disclosed a reference in the prosecution of one patent application but not in a later application. *Id.* By comparison, Smiths’ pleadings do not include any alleged facts showing that anyone associated with the prosecution of the ’493 patent even knew about

⁴ In fact, Smiths’ own pleading demonstrates that the allegedly withheld ’387 publication is cumulative to the information of record since it is “the same disclosure as the ’064 patent” that was provided to the examiner. (Dkt. 19 ¶¶ 94-95).

any of the references. (See Dkt. ¶¶ 104-109). A reasonable inference that the references were withheld with deceptive intent is not supported here. See *Exergen*, 575 F.3d at 1330-31.

Smiths' § 112 inequitable conduct allegations are similarly deficient. (Dkt. 19 ¶¶ 68-70). First, Smiths fails to meet the “who” pleading requirement because it pleads no particular facts that *any specific person knew* that claims 23-35 purportedly failed to comply with the written description and/or enablement requirements of 35 U.S.C. § 112. *Exergen*, 575 F.3d at 1329 (a general reference to “Exergen, its agents and/or attorneys” does not satisfy the “who” pleading requirement). Instead, Smiths only pleads that “*Unomedical knowingly drafted*” claims 23-35 to read on the CLEO® device “despite the fact that claims 23 through 35 are not enabled and do not comply with the written description requirement.” (Dkt. 19 ¶ 68) (emphasis added).

Smiths also fails to plead facts supporting an inference of an intent to deceive. Instead, Smiths pleads that “on information and belief,” Unomedical “knowingly” added claims 23-35 to read on the CLEO® device and knew at the time the patent issued or knows now that the claims were invalid for failure to comply with 35 U.S.C. § 112. (Dkt. 19 ¶¶ 67-70). However, similar to its faulty withholding pleading, no specific facts upon which the belief is reasonably based are pled.⁵ *Exergen*, 575 F.3d at 1330-31.

Further, a patent applicant has the right to add or amend claims during prosecution to cover a competitor's product. *Kingsdown*, 863 F.2d at 874. The allegation that Unomedical did something that it was legally entitled to do without separate, factually supported allegations of

⁵ Additionally, even if this allegation were somehow sufficient to infer deceptive intent, the §112 inequitable conduct allegation still fails because Smiths alleges knowledge at the time the patent issued or now. (Dkt. 19 ¶¶ 67-70). Instead, the relevant inquiry is whether the patentee was aware of this information during the prosecution of the patent at issue. See *Norlan Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330-31 (Fed. Cir. 2004) (noting that a patent may be rendered unenforceable if an applicant “fails to disclose material information . . . to the PTO *during* prosecution.”) (emphasis added).

intent to deceive the examiner is insufficient to support a permissive inference of deceptive intent. *See Id.* at 874-76.

Accordingly, both Smiths' withholding and its written description/enablement allegations are insufficient and should be dismissed.

B. Smiths Antitrust Counterclaims Should Be Dismissed Because It Failed To Plead Fraud (Counterclaim Counts VI, VII And VIII)

1. Applicable Legal Standard For Smiths' Antitrust Claims

The question of whether to strip a patentee of its immunity from antitrust law for activity in procuring or enforcing a patent is governed by Federal Circuit law. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). All other elements of antitrust cases are subject to the standards of the regional circuits. *Id.*

Smiths' antitrust counterclaims are based on *Walker Process* and sham litigation allegations. An antitrust plaintiff asserting a *Walker Process* claim is required first to prove that the patentee obtained the patent by knowingly and willfully misrepresenting facts to the PTO. *Id.* at 1068-69. Inequitable conduct is a broader and more inclusive concept than the common law fraud needed to support a *Walker Process* claim. *Id.* A finding of fraud in a *Walker Process* claim requires a higher threshold of both deceitful intent and materiality than do inequitable conduct claims. *Id.* at 1070-71. With *Walker Process* claims, the level of intent is not balanced against the materiality of the misrepresentation or omission; instead evidence independent of materiality is required to show the elevated threshold level of deceptive intent. *See Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007); *Nobelpharma*, 141 F.3d at 1071. If the same facts fail to suffice for inequitable conduct, they cannot support a *Walker Process* claim. *See FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1417 (Fed. Cir. 1987).

A *Walker Process* claim requires pleading that: (1) applicants made false representations or deliberate omissions of fact to the examiner that were material to patentability; (2) the misrepresentations or omissions were made with intent to deceive; (3) the examiner justifiably relied upon the false statements or omissions; and (4) but for the false statement or omission, the patent would not have been granted. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998); *MedImmune, Inc. v. Genentech, Inc.*, No. 03-2567, 2003 WL 25550611, at *9-10 (C.D. Cal. Dec. 23, 2003), *aff'd* 427 F.2d 958 (Fed. Cir. 2005), *rev'd on other grounds* 549 U.S. 118 (2007).

Sham litigation antitrust claims require showing: (1) that the suit was objectively baseless and (2) subjectively motivated by a desire to impose collateral, anticompetitive injury rather than a justifiable legal remedy. *Nobelpharma*, 141 F.3d at 1071. In other words, a sham suit must be both subjectively brought in bad faith and based on a theory of either infringement or validity that is baseless. *Id.* at 1072. A lawsuit is objectively baseless only when it is shown that no reasonable litigant could realistically expect success on the merits. *Id.* at 1071.

2. Smiths Walker Process Antitrust Claim Should Be Dismissed Because It Failed To Plead Facts Showing That Unomedical Acted With Fraudulent Intent

Smiths' *Walker Process* antitrust claim relies on its insufficient inequitable conduct allegations as support for a requisite pleading of fraud. (Dkt. 19 ¶¶ 60-151). No other basis for fraud is alleged. However, as explained above, each of Smiths' inequitable conduct allegations do not meet the *Exergen* pleading requirements and therefore cannot meet the higher pleading standard for *Walker Process* fraud. *See FMC Corp.*, 835 F.2d at 1417.

Further, even if Smiths' allegations met the inequitable conduct pleading requirements of *Exergen*, they still are insufficient to support a *Walker Process* fraud claim, which requires pleading facts sufficient to show "a clear intent to deceive the examiner and thereby cause the

PTO to grant an invalid patent.” *See MedImmune*, 2003 WL 25550611, at *9 (*quoting Nobelpharma*, 141 F.3d at 1070).

In *MedImmune*, the antitrust plaintiff pled four bases for inequitable conduct similar to the inequitable conduct allegations pled by Smiths in this case, including failing to alert the PTO to an enablement issue under 35 U.S.C. § 112; failing to disclose anticipatory prior art; and burying anticipatory prior art in voluminous documents. *Id.* at *8. The court discussed the distinct differences between pleading inequitable conduct as compared to the higher pleading standard for *Walker Process* fraud. *Id.* at *8-10. The court concluded that the inequitable conduct pleadings failed to fulfill the requirements of *Walker Process* because they suggest neither “independent or clear evidence of deceptive intent” nor that “the patent would not have issued but for the misrepresentation or omission.” *Id.* at *10. Like the antitrust plaintiff in *MedImmune*, Smiths has failed to plead facts showing that Unomedical acted with the required elevated level of deceptive intent. *See MedImmune, Inc.*, 2003 WL 25550611, at *9-10.

Furthermore, Smiths has not pled all of the elements required for showing fraud. Smiths’ answer fails to state any facts showing that the examiner relied upon the alleged misrepresentation or omission, and that but for this misrepresentation or omission, the ’493 patent would not have issued. These elements are prerequisites to a *Walker Process* claim; without them, Smiths’ antitrust counterclaims must be dismissed. *See MedImmune, Inc.*, 2003 WL 25550611, at *10; *C.R. Bard, Inc.*, 157 F.3d at 1364.

3. Smiths Has Failed To Plead Facts Establishing That This Case Is Objectively And Subjectively Baseless Sufficient To Support Its Sham Litigation Claim

Smiths’ attempts to plead that this action is objectively baseless is summarized by its conclusory allegation that “Unomedical knows the ’493 patent to be invalid, unenforceable, and/or not infringed.” (Dkt. 19 ¶¶ 62, 110, *see also* ¶¶ 61, 71). However, the facts pleaded by

Smiths do not support a claim that no reasonable litigant could realistically expect success on the merits. Instead, Smiths has done nothing more than assert garden-variety defenses of patent invalidity and noninfringement, and inequitable conduct which do not support a reasonable inference that this lawsuit is objectively baseless. *See Iqbal*, 127 S. Ct. at 1949.

With respect to patent invalidity, Smiths identifies three references as allegedly invalidating some of the '493 patent claims, and also alleges that some claims do not meet the requirements of 35 U.S.C. § 112. (Dkt. 19 ¶¶ 68, 74). However, the alleged invalidating references were all considered by the examiner during the '493 patent prosecution as indicated on the face of the '493 patent. *Molins*, 48 F.3d at 1184 (“The examiner initialed each reference, indicating his consideration of the same Absent proof to the contrary, we assume that the examiner did consider the references.”).

The Federal Circuit has noted that when the references relied upon for invalidity have been considered by the PTO, as is the case here, it is more difficult for an alleged infringer to meet its burden of proof on patent invalidity. *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008) (“When the examiner considered the asserted prior art and basis for the validity challenge during patent prosecution, that burden becomes particularly heavy.”); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1375 (Fed. Cir. 2006) (“[W]e note that the '596 patent was before the Examiner during prosecution, which makes Apotex's burden of proving invalidity at trial ‘especially difficult.’”). Similarly, part of the examination process is to determine whether the claims comply with § 112. *See* MPEP §§ 2161, 2171.

Moreover, it is well-settled that patent examiners are presumed to have done their job. *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed. Cir. 1984) (“When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has

the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job . . .”). That is one of the reasons why issued patents, such as the asserted ’493 patent in this case, are presumed valid. *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996) (“The presumption of validity is based on the presumption of administrative correctness of actions of the agency charged with examination of patentability.”).

With respect to unenforceability, as explained in Section IV.A above, Smiths has not even met the *Exergen* requirements for pleading unenforceability. With respect to noninfringement, Smiths pleads no facts about which elements from the ’493 patent are allegedly missing from the accused CLEO[®] device, let alone that Unomedical knows that these elements are purportedly missing. (Dkt. 19 ¶¶ 35-37).⁶ The only conclusion that can be drawn from the pleadings is that this lawsuit is not objectively baseless.

Further, Smiths has failed to plead facts sufficient to show that this lawsuit was brought to impose collateral, anti-competitive injury rather than to obtain a justifiable legal remedy. To make out an antitrust action for sham litigation, Smiths must plead bad faith. *Nobelpharma*, 141 F.3d at 1072; *C.R. Bard, Inc.*, 157 F.3d at 1368-69. However, Smiths only pleads that “because Unomedical knows the ’493 patent to be invalid, unenforceable, and/or not infringed, its allegations and claims in this action are brought in bad faith, are objectively baseless and a sham, and are motivated by Unomedical’s desire to impose collateral, anti-competitive injury rather than to obtain a justifiable remedy.” (Dkt. 19 ¶ 62). No facts are pled to show that Unomedical

⁶ In fact, Smiths’ allegation that Unomedical’s infringement claims is objectively baseless is rebutted by Smiths’ allegation that Unomedical drafted claims to cover the accused device. (Dkt. 19 ¶ 68). See *Fisher Tooling Co. Inc. v. Grillet Ontilliage*, No. CV 04-750 ABC (MCx) 2009 WL 58907, *10 (C.D. Cal. June 6, 2006) (holding that lawsuit not objectively baseless where accused and patented products appear similar).

had “knowledge” that the claims are allegedly invalid, not infringed or unenforceable; or that Unomedical brought this lawsuit in bad faith. Merely reciting the elements of a sham antitrust claim, as Smiths does here, does not satisfy the pleading requirements. *See Twombly*, 550 U.S. at 555.

C. Smiths’ Minnesota Antitrust Counterclaims Fail With Its Sherman Act Claims (Counterclaim VIII)

The Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66, is interpreted consistently with the federal antitrust statutes. *See Windage, LLC v. U.S. Golf Ass’n*, No. 07-4897, 2008 WL 2622965, at *4 (D. Minn. July 2, 2008); *State v. Road Constructors, Inc.*, 474 N.W.2d 224, 225 (Minn. Ct. App. 1991). Therefore, for at least the same reasons that its Sherman Act § 2 claims fail to meet the pleading standards, Smiths’ Minnesota Antitrust claims also fail.

D. Smiths’ Lanham Act Claims Should Be Dismissed Because They Are Insufficiently Plead And Fail To Include All Elements (Counterclaim Count IV)

1. Smiths Insufficiently Pled Its Lanham Act Claim Under Rule 9(b)

The Court should dismiss Smiths’ Lanham Act claim because Smiths’ conclusory and overbroad allegations do not meet the Rule 9(b) pleading standard. Courts in this district have held that Lanham Act § 43 claims are subject to the pleading requirements of Fed. R. Civ. P. 9(b). *See, e.g., CardioNet, Inc. v. LifeWatch Corp.*, No. 07 C 6625, 2008 WL 567031, at *2 (N.D. Ill. Feb. 27, 2008); *MPC Containment*, 2006 WL 2331148, at *2. Therefore, the claimant must allege “the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated.” *CardioNet*, 2008 WL 567031, at *3 (quoting *Bankers Trust Co. v. Old Republic Ins. Co.*, 959 F.2d 677, 683 (7th Cir. 1992)); *see also MPC Containment*, 2006 WL 2331148, at *2 (requiring

the “who, what, when, and where of the alleged fraud”). A court should dismiss a Lanham Act claim that fails to meet this threshold standard. *CardioNet*, 2008 WL 567031, at *3.

Smiths has wholly failed to meet these pleading requirements. First, Smiths failed to satisfy the “who” pleading requirement because it does not identify the person who made the alleged misrepresentation and instead only alleges that “Unomedical has made false statements.” (Dkt. ¶¶ 48, 56). *See CardioNet*, 2008 WL 567031, at *3 (who requirement not met where Lanham Act plaintiff only alleged that CardioNet advertised and made other statements). Smiths also fails to plead the time (when) and place (where) of the alleged misrepresentation, as required. (*See* Dkt. 19 ¶¶ 48, 56). *See CardioNet*, 2008 WL 567031, at *3. Smiths likewise failed to plead the medium or the method by which the alleged misrepresentations were made, also as required. *See id.* Finally, Smiths has failed to plead the requisite content of the misrepresentation. In *CardioNet*, the Lanham Act plaintiff alleged that “CardioNet ‘advertised and made other statements . . . to the effect that its device is superior to and/or safer than then (sic) LifeStar ACT device.’” *Id.* The court dismissed the false advertising counterclaim because “[t]hese nebulous allegations fall short of Rule 9(b)’s requirements.” *Id.* The court further noted that the allegations left both the court and CardioNet “to speculate what specific advertisements and statements underlie [the] claims.” *Id.* The same applies here where Smith only alleges that “[u]pon information and belief, Unomedical has made false statements in advertising or promotion distributed in interstate commerce, to the effect that Smiths’ products infringe the ’493 patent.” (Dkt. 19 ¶ 48). Smiths’ Lanham Act counterclaim should be dismissed.

2. Smiths’ Lanham Act Claim Fails To Sufficiently Allege Bad Faith

Smiths’ failure to plead bad faith also requires dismissal of its Lanham Act claim. A patent owner has the right to inform potential infringers of its belief that its patent may be infringed. 35 U.S.C. § 287; *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 897

(Fed. Cir. 1998). Therefore, Smiths must establish that Unomedical's alleged statements were made in bad faith. *See Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1353 (Fed. Cir. 1999).

Bad faith requires showing both objective and subjective bad faith. *Dominant Semiconductors SDN v. Osram GMBH*, 524 F.3d 1254, 1260 (Fed. Cir. 2008). However, no amount of subjective bad faith suffices to state a claim without showing that the infringement accusation was objectively baseless. *GP Indus., Inc., v. Eran Indus., Inc.*, 500 F.3d 1369, 1374 (Fed. Cir. 2007); *see also For Your Ease Only, Inc. v. Calgon Carbon Corp.*, No. 02 C 7345, 2003 WL 22169755, at *2 (N.D. Ill. Sept. 18, 2003). Further, because an allegation of bad faith is "grounded in fraud," it must be pled pursuant to Rule 9(b). *See, e.g., Vanguard Prods. Group, v. Merchandising Techs., Inc.*, No. 07-CV-1405-BR, 2008 WL 939041, at *4 (D. Or. April 3, 2008) (dismissing a Lanham Act counterclaim because the bad faith element was not pled pursuant to Rule 9(b)).

Smiths fails to plead bad faith sufficiently. Smiths only pleads that "on information and belief, these false statements were made in bad faith because Unomedical knew that the '493 patent was invalid, unenforceable, and/or not infringed by Smiths." (Dkt. 19 ¶ 49.) However, Smiths pleads no facts that establish Unomedical's "knowledge" or even facts to support Smiths' "belief." In fact, as explained in Section IV.B.3, Smiths' pleadings show that this lawsuit is not objectively baseless.

E. Smiths Minnesota Deceptive Trade Practices Act Claims Fail With Its Lanham Act Claims And Rely On An Improper Choice Of Law (Counterclaim Count V)

1. Smiths' MDTPA Claim Fails With Its Lanham Act Claim

Smiths' MDPTA claim is fatally deficient for the same reasons as its Lanham Act claim. The Rule 9(b) pleading standard also applies to Smiths' MDTPA claim. *See Masterson Personnel, Inc. v. McClatchy Co.*, No. 05-1274RHKJJG, 2005 WL 3132349, at *4-5 (D. Minn.

Nov. 22, 2005). Smiths relies on the same set of allegations to support its MDTPA claim as it does for its Lanham Act claim. Accordingly, as discussed in Section IV.D, *supra*, Smiths' MDTPA claim should be dismissed under Rule 12(b)(6) because it does not include the required factual allegations pleading the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated. *Tuttle v. Lorillard Tobacco Co.*, 118 F. Supp. 2d 954, 963-64 (D. Minn. 2000).

Moreover, Minnesota courts have held that "the [MDPTA] mirrors the Lanham Act and thus use the same analysis to evaluate false advertising claims that are made simultaneously under the federal and state statutes." *Med. Graphics Corp., v. SensorMedics Corp.*, 872 F. Supp. 643, 649 (D. Minn. 1994); *see also Alternative Pioneering Sys., Inc. v. Direct Innovative Prods., Inc.*, 822 F. Supp. 1437, 1441 (D. Minn. 1993) (analyzing only the Lanham Act claim to determine likelihood of success on the merits on all false advertising claims, including plaintiff's MDTPA claim). Therefore, because Smiths failed to plead "commercial advertising or promotion" as required under the Lanham Act, its MDTPA claim should also be dismissed. *See* section IV.D, *supra*.

2. Minnesota Law Is Not Applicable To This Case

Smiths' MDPTA claim should also be dismissed because Minnesota law is inapplicable. A district court must apply a choice-of-law analysis to determine which state's law applies to a particular set of facts alleging injury. Illinois district courts apply the choice-of-law rules of the forum in which it sits. *See, e.g., Nicholson v. Marine Corps West Federal Credit Union*, 953 F. Supp. 1012, 1015 (N.D. Ill. 1997).

Illinois law "require[s] the court to select the law of the jurisdiction that has the most significant relationship to the events out of which the suit arose, and to the parties." *Lantz v. Am. Honda Motor Co.*, No. 06 C 5932, 2007 WL 1424614, at *4 (N.D. Ill. May 14, 2007). To

determine which state's law applies, courts in this District look to: "(1) where the injury occurred; (2) where the injury-causing conduct occurred; (3) the domicile of the parties; and (4) where the relationship of the parties is centered." *Lantz*, 2007 WL 1424614, at *4. Typically, the place of injury controls unless another state has a more significant interest. *Birnberg v. Milk St. Residential Assocs. Ltd. P'ship*, Nos. 02 C 0978, 02 C 3436, 2003 WL 151929, at *15 (N.D. Ill. Jan. 21, 2003). Courts also consider where the communications that led to the purported injury took place and where the parties are located. *Cognex Corp. v. VCode Holdings, Inc.*, No. 06-1040, 2008 WL 2113661, at *35 (D. Minn. May 19, 2008).

Smiths has not pled facts sufficient to establish to whom and where the communications occurred or where the alleged injury occurred. Smiths also has not pled any facts evidencing any communications that have a significant relationship with Minnesota. (Dkt. 19 ¶¶ 43, 48). Thus, Smiths failed to plead facts sufficient to establish why Minnesota has the "most significant contacts" with its alleged injury and why the MDTPA should apply. Smiths' MDPTA claim should be dismissed.⁷

F. Smiths Tortious Interference Claims Should Be Dismissed Because Smiths Failed To Plead Bad Faith (Counterclaim Count Iii)

To state a claim for tortious interference, Smiths had to plead that Unomedical's alleged statements were made in bad faith. *See GP Indus.*, 500 F.3d at 1374. Because, as noted above, Smiths cannot establish that Unomedical's claims of infringement or that its communications regarding infringement are objectively baseless, let alone made in bad faith, Smiths tortious interference claim should be dismissed. *See Id.*

⁷ The fact that Smiths is located in Minnesota is not alone enough to establish that Minnesota has the most significant contacts with its injury because Smiths has not identified where the injurious activity occurred. *See Congex Corp.*, 2008 WL 2113661, at *35 (granting summary judgment to counter-defendant because its employee making the communication and the customer receiving it were both outside of Minnesota, and thus, Minnesota lacked significant contacts with the purported injury).

G. Smiths Patent Misuse Defense Should Be Stricken Because It Depends On The Legally Deficient Allegation In The Counterclaims (Seventh Affirmative Defense)

Smiths' patent misuse defense, should be stricken because it depends on the insufficient allegations pled in association with the defense and counterclaims discussed above. As with Smiths' Lanham Act and tortious interference claims, its patent misuse claim requires a showing of bad faith. *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1558-59 (Fed. Cir. 1995); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, Nos. 99 Civ. 8928 and 99 Civ. 9888, 61 U.S.P.Q.2d 1767, 1768 (S.D.N.Y. Oct. 26, 2001). Because Smiths has not sufficiently pled bad faith, the Court should strike Smiths' patent misuse defense.

V. CONCLUSION

For the reasons stated above, each of Smiths' Fourth, Seventh and Ninth Affirmative Defenses and its Third through Eighth Counterclaims are insufficient. Therefore, Unomedical respectfully requests that the Court strike or dismiss these Defenses and Counterclaims.

Respectfully submitted,

Dated: October 1, 2010

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CERTIFICATE OF SERVICE

The undersigned, an attorney, hereby certifies that a true and correct copy of Unomedical's Memorandum in Support of Unomedical's Motion to Strike Smiths' Fourth, Seventh and Ninth Affirmative Defenses and to Dismiss Smiths' Non-Patent Counterclaims was served on this 1st day of October, 2010, to the following attorneys:

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